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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/037,795

01/03/2002

John A. Krueger

SPEC - 6137

6948

7590

08/16/2006

Kimberly C. Diliberti
Allegiance Corporation
1430 Waukegan Road
McGaw Park, IL 60085

EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,795

Applicant(s)

KRUEGER, JOHN A.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 7/28/06 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 6 – 11 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,919,172 to Golba, Jr.

In regards to claims 6 – 11, Golba, Jr., discloses a system having an outer cannula (40); a handle portion (proximal region of 40) coupled to the end of the outer cannula; the outer cannula is adapted to removably accommodate a biopsy aspiration device therein (Col. 5, lines 6 – 8). The aspiration device includes an elongated cannula body (12) having a proximal end (14), a distal tip (16) and a linear longitudinal axis; a lumen (18) running longitudinally through the interior of the cannula body. The aspiration device includes a distal tip (16) and a laterally oriented distal opening (22) adjacent to the tip, the distal tip includes an arcuate curved surface originating on the opposite side to the laterally oriented distal opening (22) and terminating at the distal-most point of the distal opening. The proximal end of the cannula body comprises a luer attachment (20) for removable coupling of an aspiration source (Col. 3, lines 55 – 56). Golba, Jr. discloses a stylet (36) for

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removable insertion within the outer cannula. Golba, Jr. discloses the proximal end of the device including viewable indicia (21, 39) indicating the position of the laterally oriented distal opening.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6 –14 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/78590 A1 to Clark et al. in view of U.S. Patent No. 5,669,882 to Pyles.

In regards to claims 6 – 11, Clark et al. discloses a bone biopsy system including an outer cannula (16); a handle portion (12) coupled to the end of the outer cannula; the outer cannula is adapted to removably accommodate a biopsy aspiration device (80) therein (Page 9, lines 24 - 25). The aspiration device includes an elongated cannula body (82) having a proximal end (84), a distal tip (91) and a linear longitudinal axis; a lumen running longitudinally through the interior of the cannula body. The aspiration device includes a distal tip and a laterally oriented distal opening (93) adjacent to the tip. The proximal end of the cannula body comprises a luer attachment for removable coupling of an aspiration source (Page 9, lines 10 – 12). Clark et al. discloses a stylet (14) for removable insertion within the outer cannula (16; Page 6, lines 25 - 26). However, Clark et al. fails to disclose the distal tip having an arcuate curved surface originating on the opposite side to the laterally oriented distal opening and terminating at the distal-most point of the distal opening and the proximal end of the device including viewable indicia indicating the position of the laterally oriented distal opening. However, Pyles discloses an elongated cannula body (14) having a proximal

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end (20), a distal tip (16) and a linear longitudinal axis; a lumen (18) running longitudinally through the interior of the cannula body (Col. 3, lines 25 – 26), the lumen terminating at a proximal opening (22) and terminating at a single laterally oriented distal opening (48) immediately adjacent the distal tip (Col. 4, lines 2 – 3); wherein the tip of the cannula body comprises an arcuate curved surface (Col. 3, line 19) originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening, the proximal end of the device including viewable indicia (24) indicating the position of the laterally oriented distal opening (Figure 2). It would have been obvious to one having ordinary skill in the art to modify the distal tip of the aspiration device as disclosed by Clark et al. to include an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening as taught by Pyles in order to allow for rotation of the needle during use with a decreased chance of cutting the tissue of the patient (Col. 4, lines 5 – 8) and to improve directional control by the physician during rotation of the needle (Col. 4, lines 9 - 11). It would have been obvious to one having ordinary skill in the art to modify the proximal end to the device as disclosed by Clark et al. to include viewable indicia indicating the position of the laterally oriented distal opening as taught by Pyles to allow the user to be aware of the direction of the opening when inserted into the patient.

In regards to claims 12 – 14, Clark et al. discloses a method for obtaining a bone marrow sample from a marrow site in a patient including penetrating the cortex of a bone with an outer cannula having a stylet positioned within (Page 9, line 33 – Page 10, line 4), the distal portion of the stylet extending beyond the end of the outer cannula, until the distal end is surrounded by marrow; removing the stylet (Page 10, line 4); inserting into the outer cannula a biopsy aspiration device such that the distal tip of the aspiration device is extended into marrow (Page 10, lines 5 - 7). Clark et al.

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discloses attaching an aspiration source to the proximal end of the aspiration device and withdrawing a sample of marrow from the sampling site (Page 10, lines 7 - 10). Clark et al. discloses rotating the aspiration device within the outer cannula thereby repositioning the laterally oriented distal opening (Page 10, lines 21 - 25). Clark et al. discloses removing the aspiration device from the outer cannula and advancing the outer cannula into the bone to obtain a core sample (Page 10, lines 26 - 28). Clark et al. discloses the aspiration device including an elongated cannula body (82) having a proximal end (84), a distal tip (91) and a linear longitudinal axis; a lumen running longitudinally through the interior of the cannula body. The aspiration device includes a distal tip and a laterally oriented distal opening (93) adjacent to the tip. However, Clark et al. fails to disclose the distal tip having an arcuate curved surface originating on the opposite side to the laterally oriented distal opening and terminating at the distal-most point of the distal opening. However, Pyles discloses an elongated cannula body (14) having a proximal end (20), a distal tip (16) and a linear longitudinal axis; a lumen (18) running longitudinally through the interior of the cannula body (Col. 3, lines 25 - 26), the lumen terminating at a proximal opening (22) and terminating at a single laterally oriented distal opening (48) immediately adjacent the distal tip (Col. 4, lines 2 - 3); wherein the tip of the cannula body comprises an arcuate curved surface (Col. 3, line 19) originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening. It would have been obvious to one having ordinary skill in the art to modify the distal tip of the aspiration device as taught by Clark et al. to include an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening as taught by Pyles in order to allow for rotation of the needle during use with a decreased chance of cutting the tissue of the patient (Col. 4,

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lines 5 – 8) and to improve directional control by the physician during rotation of the needle (Col. 4, lines 9 - 11).

Response to Arguments

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


JMLF


MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700